IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Continuation Reissue Application of:	)	
	)	
Uber, III et al.	)	
	)	Art Unit: 3737
Serial No. 09/545,582	)	
	)	Examiner: R. Smith
Filed: April 7, 2000	)	
	)	
For: Patient Infusion System for Use With MRI	)	

DECLARATION OF DR. BRUCE ROSEN PURSUANT TO 37 C.F.R. § 1.132

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir or Madam:

I, Dr. Bruce Rosen, hereby declare that:

I. INTRODUCTION

1. I am currently the Director of the Massachusetts General Hospital ("MGH") Nuclear Magnetic Resonance Center, and a Professor of Radiology at the Harvard Medical School. I have worked in the field of magnetic resonance imaging (MRI) for over 20 years, have published over 219 articles in the field along with 39 book chapters, and I have been awarded the Gold Medal for my work in the field of Functional Magnetic Resonance Imaging by the International Society of Magnetic Resonance in Medicine.

2. I received my undergraduate degree in Astronomy and Astrophysics at Harvard University in 1977, my master's degree in physics at Massachusetts Institute of Technology

("MIT") in 1980, my medical degree at Hahnemann Medical College in Philadelphia, PA in 1982 and my Ph.D. in Medical Physics at MIT in 1984.

3. I have knowledge of and experience with medical devices relating to magnetic resonance imaging based on my education, experience as a professor of radiology, teaching and performing research in the areas of biomedical and clinical physics and magnetic resonance imaging, and as a clinical and research fellow in the Radiology department at MGH. My work has included the designing of a magnetic resonance imaging spectrometer and working on design teams to determine specifications for electrical equipment used as part of magnetic resonance imaging experiments. I have previously worked as an expert in patent cases involving magnetic resonance imaging technology, including but not limited to *Medrad, Inc. v. Tyco Healthcare Group LP et al.*, Civil Action No. 01-1997 (GLL) (W.D. Pa.), which involved allegations surrounding United States Patent No. RE37,602, a patent that is related to the current Patent Application.

4. I am familiar with the design, development, operation, effectiveness and other characteristics of the patient infusion system which forms the basis of U.S. Pat. App. No. 09/545,582, entitled "Patient Infusion System for Use with MRI," hereinafter referred to as the Patent Application.

5. Based on my education and work experience, at the time of the invention claimed in the Patent Application, I was, and still am, a person having ordinary skill in the art of radiology and related aspects, such as designing devices to effectively operate in the MRI environment.

II. CHALLENGES IN DESIGNING AN INJECTOR IN THE MR ENVIRONMENT

6. Designing an injection system that can operate successfully in an MRI environment is challenging. An injector for MRI must not emit electromagnetic interference or "noise" that would disrupt the highly sensitive magnetic field of the MRI scanner and cause flaws in the images produced by the MRI scanner. Further, an MRI injector must be designed in a way to ensure that the MRI scanner would not detrimentally affect or degrade the operational performance of the injector.

7. While at MGH, I assisted Medrad with testing prototype injector devices to be used with MR imaging systems (prototypes created during development of the invention in the Patent Application). I personally used one of the prototype devices and noted that, at that time, the device did not work effectively in the MRI environment. In particular, the device interfered with the acquisition of images by the MRI system. The prototype device was different than the design and operation of the Spectris injector that MGH currently uses.

III. COMMERCIAL SUCCESS

8. Medrad's Spectris injector was, to my knowledge, the first injector sold in the United States that could successfully operate in an MRI suite. I understand that the Spectris injector embodies the pending claims of the Patent Application. While working at MGH, I have used the Spectris injector to inject patients with contrast medium in conjunction with MRI procedures. The Spectris injector has worked and continues to work effectively to deliver contrast medium to patients in specifically programmed quantities during MRI procedures.

9. The Spectris injector has several components:

a. Two components reside in the control room, which is outside of the shielded scan room. These components include the input device where an operator would program the injector.

b. Two other components reside in the shielded scan room. These components include the motors to drive the syringes and the injector head, which holds two fluid syringes from which fluid is to be injected.

c. The components in the control room are connected to the components inside the shielded scan room via a communication link. A part of the communication link includes two infrared transceivers that communicate through the shielded window.

10. The use of Medrad's Spectris injector during MRI procedures does not create spurious electromagnetic interference that adversely affects the images obtained while the injector is being used. The images obtained by the MRI system while the Spectris injector is in operation do not include artifacts that typically result from such interference. Medrad's Spectris injector assists our facility in making MR images that are diagnostically beneficial.

11. Also, when in use, the strong magnetic fields of the MRI imaging system do not adversely affect the operation of the Spectris injector. That is, the motors and other electronic components of Medrad's Spectris injector operate effectively while the MRI system is acquiring images.

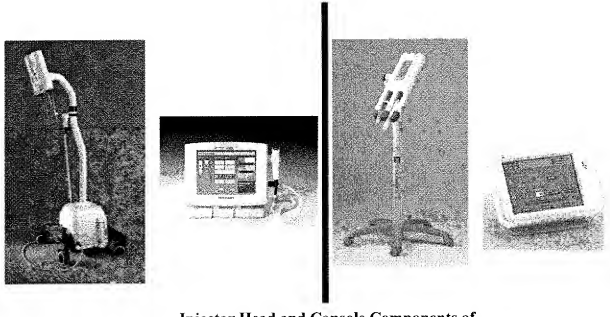
12. Medrad's Spectris injector, therefore, is commercially desirable because it operates effectively in an MRI suite – a harsh environment for electronic devices – without adversely affecting the sensitive MR imaging system and without being adversely affected by the strong magnetic fields of the imaging system.

13. I understand that evidence of secondary considerations, such as commercial success of the product that embodies the claimed invention, is one of the four inquiries for determining if an invention is obvious. The high level of commercial success of Medrad's Spectris and, and the successor to the Spectris, the Spectris Solaris injector, is evidence that the invention claimed in the Patent Application is not obvious.

IV. COPYING OF CLAIMED INVENTION BY APPLICANTS' COMPETITOR

14. I also understand that Applicant's competitor Tyco Healthcare Group LP ("Tyco Healthcare") has sold in the United States an MR injector that copies the features of the claimed invention.

15. Figure 1 (below) is a side-by-side comparison of key components (injector head and console components) of Applicants' commercial embodiment of the invention of the Patent Application (on the left) and the corresponding and equivalent components of Tyco Healthcare's competing product (on the right), the Optistar injector.



Injector Head and Console Components of Applicants' Spectris Solaris Injection System and Tyco Healthcare's Optistar Injector

Figure 1

16. Tyco Healthcare's Optistar injector, on the right in Figure 1 above, is comprised of components that have the same features and functions as the invention claimed in the Patent Application. The Console of Tyco Healthcare's Optistar injector, which is located outside the shielded MR room, controls and regulates the entire injection system. The Console is connected to a component inside the shielded room called the Power Control (not shown in Figure 1) by a substantially non-reactive communication control link, which transmits control information to and from the shielded room without interfering with the MR system. The Power Control component receives control information from the Console and drives the syringes that are located in the injector head component (the component on the left in Figure 1).

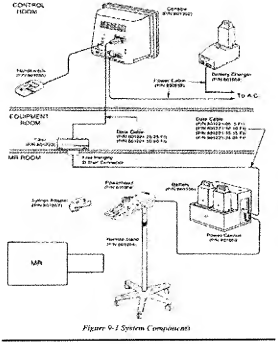


Figure 9-1 System Components

Schematic Diagram of Optistar Injector Showing Location of Components

Figure 2

17. Figure 2 (above) is a diagram from the Service Manual of Tyco Healthcare's Optistar injector showing the physical layout and location of the components of the Optistar. The diagram shows the "Console" (*system controller*) in the Control Room, which is outside of the shielded scan room. The diagram also shows the "Power Control" component (*infusion apparatus control means*) or (*injector control unit*) inside the shielded scan room along with the "Powerhead" component (*injector*). The diagram further shows the data cables (*communication control link*) connecting the Console to the Power Control. It can be seen that the components of the Optistar injector have the same system architecture as the claimed invention and are positioned in the same locations as the components of the claimed invention.

18. I understand that evidence of copying the product that embodies the claimed invention is part of the secondary considerations of non-obviousness. The evidence of copying of Medrad's Spectris injector by Tyco Healthcare is evidence that the invention claimed in the Patent Application is not obvious.

V. THE CLAIMED INVENTION WAS NOT OBVIOUS

19. It is my understanding that the pending Claims of the Patent Application have been rejected under 35 U.S.C. § 103(a) as being unpatentable over a combination of alleged prior art references.

20. I am very familiar with the patient infusion system for use with MRI in the Patent Application. I have reviewed the Examiner's December 1, 2006 rejection and the prior art cited by the Examiner in that rejection. I respectfully submit that the examiner's rejection of the pending claims of the Patent Application based on those references was improper because the invention claimed in the Patent Application would not have been obvious to a person having ordinary skill in the art. I have provided a more detailed response below.

A. "Applicant's Admission of the Prior Art"

21. I understand that the Examiner rejected all of the pending Claims of the Patent Application in view of the "Applicant's admission of the prior art." *See* Dec. 1, 2006 Office Action. It is my understanding that the Examiner cited Medrad's own work on its prototype devices as the admission of prior art, and it is further my understanding, that an Applicant's own work cannot be used as prior art against the Patent Application.

B. The Two Drive Mechanisms Feature of the Claimed Invention Was Not Obvious

22. I understand that the Examiner rejected Claims 62 and 118-128, which require two syringes and two drive mechanisms, in view of a combination of references including (1) the *Saini et al.*, Technical Report: In Vitro Evaluation of a Mechanical Injector for Infusion of Magnetic Resonance Contrast Media, Investigative Radiology, Vol. 26/ No. 8, Aug. 1991, MD123695-99 (the *Saini et al.* article) and (2) the Mark V Injection System materials. The Examiner noted that the combination of those references failed to disclose two syringes and two drive mechanisms but that a person of ordinary skill in the art would have known to modify the injector disclosed in those references to include two drive mechanisms. I respectfully submit that the Examiner's rejection was improper.

23. I, along with my fellow co-authors of *Saini et al.*, recognized the problem of having a single drive mechanism in the text of the article and proposed solutions for overcoming the problem. (*Id.* at 751(MD123699)). These solutions however were not closely related to the invention claimed in the Patent Application, and they in fact teach away from the two drive mechanisms that are part of the present invention. (*Id.*).

24. The first solution identified by us was to aspirate contrast solution into a syringe that was already preloaded with saline solution – essentially layering contrast solution and saline solution in a single syringe. (*Id.*). The second solution included incorporating different compartments in a single syringe. (*Id.*). The two syringes and two drive mechanisms of the claimed invention do not read on these solutions and these solutions teach away from the claimed invention.

25. I respectfully submit that the Examiner therefore improperly concluded that it would have been obvious to a person skilled in the art to incorporate a second drive mechanism to engage the second syringe based on the *Saini et al.* article and the Mark V injector materials. I was a person of ordinary skill in the art who used the Mark V injection system and it was not obvious to me, or my co-authors, at the time of the invention to incorporate two drive mechanisms to engage two syringes. As a result, pending Claims 62 and 118-128 are allowable and the Examiner's rejection of those claims should be withdrawn.

C. The Substantially Non-Reactive Communication Control Link Feature Was Not Obvious

26. I also understand that the Examiner rejected all of the pending Claims under Section 103 in view of the *Kalik et al.,Patient Ane sthesia & Monitoring at a 1.5-T MRI Installation*, Magnetic Resonance in Medicine 7, pp. 210-221, MAL-PIT-022891-901 (the *Patient Anesthesia & Monitoring* article) in combination with other references. The Examiner cited this reference's use of fiber optic communication links in the MR environment to prevent EM interference as showing a "communications link between the external controller and the injector unit" that has the advantage of preventing "EM interference from affecting the system operation." *See, e.g.*, Examiner's Dec. 1, 2006 Rejection at pp. 2-3. I respectfully submit that

the Examiner's application of the *Patient Anesthesia and Monitoring* reference is improper for two principal reasons.

27. First , the Examiner's application of this reference was improper because the claimed invention requires a *communication control link*, and as the Examiner stated in the rejection, the *Patient Anesthesia and Monitoring* article only shows a "communications link." The link described in the *Patient Anesthesia & Monitoring* article does not transmit control information as required by all of the pending Claims of the Patent Application. Nor does the link disclosed in the *Patient Anesthesia & Monitoring* article connect a control component located outside the shielded room with a control component inside the shielded room – another requirement of all the pending claims.

28. Second, the article teaches away from the invention claimed in the Patent Application because it describes systems with an architecture where the integrity of the shielded perimeter is breached and some RF interference is observed. (*See Patient Anesthesia & Monitoring*, at 219). This teaches away from the invention of the Patent Application. (*Id.*).

29. Therefore, the *Patient Anesthesia & Monitoring* article does not disclose a *communication control link* that is *substantially non-reactive* with the magnetic resonance imaging system. As a result, this claim limitation is not disclosed in the prior art, all of the pending claims are allowable and the rejection of the pending claims on this basis should be withdrawn by the Examiner.

D. A Person Having Ordinary Skill in the Art Would Not Have Been Motivated to Combine the References Cited by the Examiner

30. At the time of the invention claimed in the Patent Application, I and others in the field recognized the need for an injector that was capable of working in the MRI environment.

Medrad's solution, embodied in the Spectris injector and claimed in the Patent Application, did not occur to me or my colleagues at the time of Medrad's invention.

31. Medrad's Spectris injector was the first commercially used injector in the MR environment. The mere fact that no other prior art devices were available to provide contrast media to patients during MRI procedures demonstrates that the Examiner's combination would not have occurred in the ordinary course.

32. At the time of the invention, a person of ordinary skill in the art would not have been motivated to combine the references cited above because they teach away from distributing the control aspects of the system between components inside and outside. The *Saini et al.* article teaches a single control component located inside the shielded room, the Mark V injector has all of the control in the components outside the shielded room and *Patient Anesthesia & Monitoring* teaches either having all the control either inside or outside, but not distributed between components at both locations. Therefore, these references teach away from their combination.

33. Further, these references identified RF interference as a concern, however they did not provide an adequate solution to the problem nor did they provide the solution claimed in the Patent Application. The *Saini* article did not disclose whether the system was reactive with the magnetic fields of the imaging system other than the static field (B_0). Similarly, the *Patient Anesthesia & Monitoring* article noted that the systems disclosed therein created RF interference and did not provide a solution for the problem. The Mark V injector was designed for the angiographic or CT environment and therefore did not address this issue. Therefore, a person having ordinary skill in the art would not have known or been motivated to combine these references.

34. Therefore, the pending Claims are allowable and the Examiner's rejection of the pending Claims on the basis of the combination of *Saini et al.,Patient A nesthesia and Monitoring* and the Mark V materials should be withdrawn.

D. The References Cited by the Examiner, Even if Combined the References Cited by the Examiner

35. As identified in Paragraph 30 above, the combination of *Saini et al.,Patient Anesthesia and Monitoring* and the Mark V materials does not disclose two control components, one inside and one outside the shielded room, connected by a substantially non-reactive communication control link. I respectfully submit therefore that the Examiner's rejection was improper for this reason as well and that the Examiner's rejection of the pending claims based on this combination of references should be withdrawn.

VI. GENERAL INFORMATION

36. As noted above, I have worked as an expert in *Medrad, Inc. v. Tyco Healthcare Group LP et al.*, Civil Action No. 01-1997 (GLL) (W.D. Pa.). In that case I was hired and paid by Medrad to testify on a variety of issues, including infringement and validity of United States Patent RE37,602, which is related to the invention claimed in the Patent Application at issue here. Also, upon occasion, Medrad provides MGH with devices for evaluation purposes. I am not, however, being paid or otherwise compensated for providing this declaration.

37. I declare under penalty of perjury that the foregoing is true and correct.

Executed on May 30, 2007

Dr. Bruce Rosen
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